

***Remarks***

***I. Support for Amendments***

Reconsideration of this Application is respectfully requested.

By the foregoing amendments, claims 1, 5, 7, 8, 15, 16, 23, 26, 92, 93, 97, 98 and 102 are sought to be amended. Support for amended claim 1 is found throughout the specification and original claims as filed, *inter alia*, in paragraphs [0054-0055] and [0063] of the present specification (U.S. published application 2006/0204475). The amendments to claims 5, 8 and 26 are sought to delete subject matter. The amendments to claims 7, 15 and 16 are sought to place these claims into proper U.S. format. Support for amended claim 23 is found throughout the specification and original claims as filed, *inter alia*, original claim 24. Support for amended claims 92, 93, 97, 98 and 102 is found throughout the specification and original claims as filed, *inter alia*, in paragraphs [0024] and [0256-0265] of the present specification.

New claims 104-126 are sought to be added. New claims 104-108 are supported by the originally filed claims and specification including, *inter alia*, in paragraphs [0055-0056] of the present specification. New claim 109 is supported by the originally filed claims and specification including, *inter alia*, in original claim 8. New claim 110 is supported by the originally filed claims and specification including, *inter alia*, in original claim 9. New claim 111 is supported by the originally filed claims and specification including, *inter alia*, in original claim 10. New claims 112, 113 and 120 are supported by the originally filed claims and specification including, *inter alia*, in paragraph [0178] of the present specification. New claim 114 is supported by the originally filed claims and specification including, *inter alia*, in original claim 21. New claims 115 and 116 are

supported by the originally filed claims and specification including, *inter alia*, in paragraph [0097] of the present specification. New claim 117 is supported by the originally filed claims and specification including, *inter alia*, in original claim 25. New claims 118 and 125 are supported by the originally filed claims and specification including, *inter alia*, in paragraph [0063] of the present specification. New claim 119 is supported by the originally filed claims and specification including, *inter alia*, in original claim 32. New claim 121 is supported by the originally filed claims and specification including, *inter alia*, in original claims 8 and 21. New claim 122 is supported by the originally filed claims and specification including, *inter alia*, in original claims 9 and 10. New claim 123 is supported by the originally filed claims and specification including, *inter alia*, in original claim 14. New claim 124 is supported by the originally filed claims and specification including, *inter alia*, in original claims 27 and 43. New claim 126 is supported by the originally filed claims and specification including, *inter alia*, in original claim 16.

Applicants respectfully submit that these amendments place the application in condition for allowance and do not raise any new issue requiring further search or examination. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

## ***II. Status of the Claims***

Upon entry of the foregoing amendments, claims 1, 2, 5, 7-9, 11, 12, 14-16, 18, 21-23, 26, 27, 28, 30, 32, 38, 46, 89-94, and 97-126 are pending in the application, with claim 1 being the sole independent claim. Claim 3, 4, 6, 10, 13, 17, 19, 20, 25, 29, 31, 33-37, 39-45, 47-88, 95 and 96 were cancelled previously and claim 24 has been cancelled herewith without prejudice to or disclaimer of the subject matter therein. Claims 1, 5, 7, 8, 15, 16, 23, 26, 92, 93, 97, 98 and 102 have been amended. New claims 104-126 are sought to be added. As discussed above, these amendments add no new matter to the present application.

## ***III. Claim Rejections - 35 U.S.C. § 112***

### ***A. Rejections Under 35 U.S.C. §112, Second Paragraph***

In the Office Action at page 3, the Examiner has rejected claims 1, 2, 5, 7, 9, 11, 12, 14-16, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94 and 97-103 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinct claim the subject matter which Applicants regard as the invention.

In making this rejection of claim 1, the Examiner alleges the that phrase "a human melanoma MelanA peptide analogue" is indefinite. Solely to advance prosecution and not in acquiescence to the Examiner's rejection, Applicants have amended claim 1 (and thus the claims depending therefrom) to include "wherein said antigen or antigenic determinant comprises a human melanoma MelanA peptide analogue that comprises an amino acid sequence derived from the amino acid sequence of SEQ ID NO:78 or SEQ ID NO:79 by alteration of one or two amino acid(s) or amino

acid derivative(s) in said amino acid sequence, wherein said alteration comprises an amino acid substitution, deletion or insertion or a combination thereof." Applicants believe that this amendment clearly specifies the metes and bounds of the term "human melanoma MelanA peptide analogue" and respectfully request that the rejection of claim 1, and of claims 2, 9, 11, 12, 14, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94 97-103 which depend from claim 1, be reconsidered and withdrawn.

Additionally, the Examiner requests clarification of the phrase "bound to said virus-like particle" in claim 1. The Examiner suggests that claim 1 can be clarified by the amendment to "bound to or packaged in said virus-like particle." Solely to advance prosecution and not in acquiescence to the Examiner's rejection, Applicants have amended claim 1 to include "wherein said immunostimulatory substance is packaged into said virus-like particle." Applicants therefore respectfully request that the rejection of claim 1 and all claims that depend therefrom be reconsidered and withdrawn.

At page 3 of the Office Action, the Examiner requests clarification on whether the phrase "has an amino sequence" in claims 7, 15 and 16 should be read as "consists of the sequence," "comprises the sequence," or "comprises any part of the sequence." Solely to advance prosecution and not in acquiescence to the Examiner's rejection, Applicants have amended claims 7, 15 and 16 to include the term "comprises." Applicants therefore respectfully request that the rejection of claims 7, 15 and 16 be reconsidered and withdrawn.

***B. Rejections Under 35 U.S.C. § 112, First Paragraph***

In the Office Action at page 3, The Examiner has rejected claims 92-94 and 97-103 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a useful immunogenic composition, allegedly does not reasonably provide enablement for a vaccine. Applicants respectfully disagree with this contention. However, solely to advance prosecution and not in acquiescence to the Examiner's rejection, Applicants have amended claims 92, 93, 97, 98 and 102 to recite "an immunogenic composition." The Examiner has acknowledged that the specification fully enables claims reciting an immunogenic composition. *See* Office Action, p. 3. Accordingly, Applicants respectfully request that the enablement rejection of claims 92-94 and 97-103 be reconsidered and withdrawn.

***IV. Obviousness-Type Double Patenting***

***A. U.S. Appl. No. 10/550,518***

In the Office Action at page 4, claims 1, 2, 5, 7-9, 11, 12, 14-16, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, and 97-103 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7, 8, 10, 13-20, 34, 35, 100, 119-121, 126, 127 and 138-145 of copending U.S. Appl. No. 10/550,518.

Applicants respectfully traverse the Examiner's rejection. However, solely to advance prosecution, and not in acquiescence to the rejection, Applicants provide herewith a Terminal Disclaimer under 37 C.F.R. § 1.32(c) of the term of any patent granted on this application which would extend beyond the expiration date of a patent

granted on U.S. Application No. 10/550,518. Applicants respectfully request the consideration and entry of this Terminal Disclaimer, and the reconsideration and withdrawal of the present obviousness-type double patenting rejection.

***B. U.S. Appl. No. 10/244,065***

In the Office Action at pages 4-5, claims 1, 2, 5, 7-9, 11, 12, 14-16, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, and 97-103 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-53, 56-77, 79-128, 132-154 and 184-207 of copending Appl. No. 10/224,065.

Applicants respectfully traverse the Examiner's rejection. However, solely to advance prosecution, and not in acquiescence to the rejection, Applicants provide herewith a Terminal Disclaimer under 37 C.F.R. § 1.32(c) of the term of any patent granted on this application which would extend beyond the expiration date of a patent granted on U.S. Application No. 10/224,065. Applicants respectfully request the consideration and entry of this Terminal Disclaimer, and the reconsideration and withdrawal of the present obviousness-type double patenting rejection.

***C. U.S. Appl. No. 10/563,944***

In the Office Action at page 5, claims 1, 2, 5, 7-9, 11, 12, 14-16, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, and 97-103 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 10, 14-16, 33, 34, 41, 48, 50, 55, 57, 63 and 64 of copending Appl. No. 10/563,944.

The priority date of the '944 application is July 10, 2003, whereas the priority date of the present application is March 26, 2003. Applicants note that the priority date of the '944 reference application used in making this obviousness-type double patenting rejection is *after* the priority date of the present application. Hence, the present application is "the earlier filed application of the two pending applications" as that phrase is meant in MPEP § 1490.V.D. Applicants believe that the amendments and arguments presented herein will place the present application in condition for allowance except for the ODP rejection. Thus, Applicants request the Examiner to hold this rejection in abeyance until the arguments and amendments herewith have been considered, and to reconsider and withdraw this rejection upon allowance of the present claims in accordance with MPEP § 1490.V.D.

***D. U.S. Appl. No. 11/663,350***

In the Office Action at pages 5-6, claims 1, 2, 5, 7-9, 11, 12, 14-16, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, and 97-103 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12, 14-19 and 23 of copending Appl. No. 11/663,350.

The priority date of the '350 application is September 21, 2004, whereas the priority date of the present application is March 26, 2003. Applicants note that the priority date of the '350 reference application used in making this obviousness-type double patenting rejection is *after* the priority date of the present application. Hence, the present application is "the earlier filed application of the two pending applications" as that phrase is meant in MPEP § 1490.V.D. Applicants believe that the amendments and

arguments presented herein will place the present application in condition for allowance except for the ODP rejection. Thus, Applicants request the Examiner to hold this rejection in abeyance until the arguments and amendments herewith have been considered, and to reconsider and withdraw this rejection upon allowance of the present claims in accordance with MPEP § 1490.V.D.

***V. Claim Rejections - 35 U.S.C. § 102(e)***

In the Office Action at page 6, claims 1, 2, 9, 11, 12, 14, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, and 97-103 have been rejected under 35 U.S.C. § 102(e) as being anticipated by US 2003/0099668.

As the Examiner has indicated at page 6 of the Office Action, the present rejection under 35 U.S.C. § 102(e) may be overcome by a showing under 37 C.F.R. § 1.132. To this end, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 by Martin Bachmann, Edwin Meijerink and Katrin Schwarz, who are inventors common to the '668 application and to the present application. The Declaration states that the subject matter common to both applications was invented by Martin Bachmann, Edwin Meijerink and Katrin Schwarz. Thus the disclosure of the subject matter in the '668 application which is claimed in the present application but not in the '668 application does not qualify as an invention "by another" for the purposes of 35 U.S.C. § 102(e). Applicants therefore respectfully request this rejection be reconsidered and withdrawn.

***VI. Claim Rejections - 35 U.S.C. § 103(a)***



In the Office Action at pages 6-7, claims 5, 7, 8, 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being obvious over US 2003/0099668 in view of Blanchet et al. (*Journal of Immunology* 167:5858-5861, 2001).

As the Examiner has indicated at page 7 of the Office Action, the present rejection under 35 U.S.C. § 103(a) may be overcome by a showing under 37 C.F.R. § 1.132. To this end, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 by Martin Bachmann, Edwin Meijerink and Katrin Schwarz, who are inventors common to the '668 application and to the present application. The Declaration states that the subject matter common to both applications was invented by Martin Bachmann, Edwin Meijerink and Katrin Schwarz. Thus the disclosure of the subject matter in the '668 application which is claimed in the present application but not in the '668 application does not qualify as an invention "by another" for the purposes of 35 U.S.C. § 103(a). Applicants therefore respectfully request this rejection be reconsidered and withdrawn.

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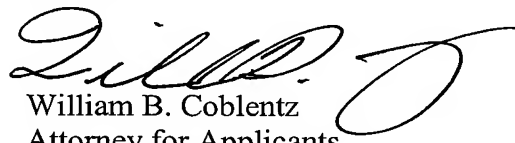
***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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